DOCKET NO.: OGS-0002/P0055-USW01 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Terence D. Butters, et al. **Confirmation No.: Not Yet Assigned**

Application No.: 10/618,165 **Group Art Unit: Not Yet Assigned**

Filing Date: July 11, 2003 **Examiner: Not Yet Assigned**

For: PHARMACEUTICALLY ACTIVE PIPERIDINE DERIVATIVES

DATE OF DEPOSIT: December 10, 2003

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Elizabeth A. McLoud

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date

of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of **$180.00** as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of **$180.00** as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **$180.00** as set forth in § 1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

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☐ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

EXCEPT THAT:

☒ In view of the voluminous nature of references **7 and 15**, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C.§ 120 have been made in the instant application:

☐ Copies of references **[list as appropriate]** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. , filed .

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

☐ The relevance of those listed references which are not in the English language is as follows:

☒ English language abstracts have been provided for references **28 and 29** which are not in the English language.

Date: December 10, 2003

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Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. OGS-0002/ P0055-USw01	Application No. 10/618,165
	Applicant Terence D. Butters, et al.	
	Filing Date July 11, 2003	Group Not Yet Assigned
	Confirmation No. Not Yet Assigned	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	1	Abe, A., et al., "Reduction of globotriaosylceramide in fabry disease mice by substrate deprivation," *J. of Clin. Invest.*, June **2000**, *105(11)*, 1563-1571
	2	Asano, N., et al., "Novel α-L-fucosidase inhibitors from the bark of *angylocalyx pynaertii* (leguminosae), *Eur. J. Biochem.*, **2001**, *268*, 35-41
	3	Asano, K., "New entry for asymmetric deoxyazasugar synthesis: syntheses of deoxymannojirimycin, deoxyaltrojirimycin and deoxygalactostatin," *Chem. Commun.*, **1999**, 41-42
	4	Barili, P.L., et al., "Double reductive amination of L-*arabino*-Hexos-5-uloses: a diastereoselective approach to 1-deoxy-D-galactostatin derivatives (#)(°)," *Tetrahedron*, **1997**, *53(9)*, 3407-3416
	5	Baxter, E.W., et al., "Expeditious synthesis of azasugars by the double reductive amination of dicarbonyl sugars," *J. Org. Chem.*, **1994**, *59*, 3175-3185
	6	Bernotas, R.C., et al., "Efficient preparation of enantiomerically pure cyclic aminoalditols total synthesis of 1-deoxynojirimycin and 1-deoxymannojirimycin," *Tetrahedron Letts.*, **1985**, *26(9)*, 1123-1126
*	7	Biochemical Genetics, A Laboratory Manual, Oxford University Press
	8	Chen, C.-S., et al., "Abnormal transport along the lysosomal pathway in mucolipidosis, type IV disease," *Proc. Natl. Acad. Sci. USA*, May **1998**, *95*, 6373-6378
	9	Cox, T., et al., "Novel oral treatment of gaucher's disease with N-butyldeoxynojirimycin (OGT 918) to decrease substrate biosynthesis," *The Lancet*, April 29, **2000**, *355*, 1481-1485
	10	Fouace, S., et al., "Lipophilic prodrugs of 1-deoxynojirimycin derivatives," *Tetrahedron Letts.*, **2000**, *41*, 7313-7315
EXAMINER		**DATE CONSIDERED**

* A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and easily obtainable by the Examiner.

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	11	Fowler, P.A., et al., "Synthesis and activity towards yeast α-glucosidase of 1,5-dideoxy-1,5 imino-L-iditol (1-deoxy-L-idonojirimycin)," *Carbohydrate Res.*, **1993**, *246*, 377-381
	12	Godskesen, M., et al., "Deoxyiminoalditols from aldonolactones – V. preparation of the four stereoisomers of 1,5-dideoxy-1,5-iminopentitols. Evaluation of these iminopentitols and three 1,5-dideoxy-1,5-iminoheptitols as glycosidase inhibitors," *Bioorganic & Medicinal Chem.*, **1996**, *4(11)*, 1857-1865
	13	Goodman, L.A., et al., "Ectopic dendrites occur only on cortical pyramidal cells containing elevated GM2 ganglioside in α-mannosidosis," *Proc. Natl. Acad. Sci. USA*, December **1991**, *88*, 11330-11334
	14	Grandel, R., et al., "A short synthesis of azasugars via aldol reaction of chelated amino acid ester enolates," *Tetrahedron Letts.*, **1997**, *38(46)*, 8009-8012
*	**15**	Greene, et al., Protective Groups in Organic Chemistry, 2nd Ed., *Wiley-Interscience, NY*, **1991**
	16	Hügel, H.M., et al., "Stereoselective electrophilic cyclizations of δ-aminoalkenes derived from carbohydrates: synthesis of polyhydroxypiperidines," *Aust. J. Chem.*, **1998**, *51*, 1149-1155
	17	Ikota, N., et al., "Improved synthesis of 1-deoxynojirimycin and facile synthesis of its stereoisomers from (S)-pyroglutamic acid derivative," *Heterocycles*, **1997**, *46*, 637-643
	18	Jeyakumar, M., et al., "Delayed symptom onset and increased life expectancy in sandhoff disease mice treated with *N*-butyldeoxynojirimycin," Proc. *Natl. Acad. Sci. USA*, May **1999**, *96*, 6388-6393
	19	Kajimoto, T., et al., "Palladium-mediated stereocontrolled reductive amination of azido sugars prepared from enzymatic adol condensation: a general approach to the synthesis of deoxy aza sugars," *J. Am. Chem. Soc.*, **1991**, *113*, 6678-6680
	20	Kazmaier, U., et al., "A short synthesis of polyhydroxylated piperidines by adol reaction of chelated amino acid ester enolates," *Eur. J. Org. Chem.*, **1998**, 1833-1840

EXAMINER	**DATE CONSIDERED**

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	21	Lee, B.W., et al., "A short and efficient synthesis of 2R,3R,4R-3,4-dihydroxyproline, 1,4-dideoxy-1,4-imino-L-xylitol, 2R,3R,4R,5S-3,4,5-trihydroxypipecolic acid, and 1,5-dideoxy-1,5-imino-L-iditol," *Synthesis*, **2000**, *9*, 1305-1309
	22	Le Merrer, Y., et al., "Synthesis of azasugars as potent inhibitors of glycosidases," *Bioorganic & Medicinal Chem.*, **1997**, *5(3)*, 519-533
	23	Liotta, L.J., et al., "A new class of endoglycosidase inhibitors. Studies on endocellulases," *J. Am. Chem. Soc.*, **1989**, *III*, 783-785
	24	Liu, Y.-Y., et al., "Uncoupling ceramide glycosylation by transfection of glucosylceramide synthase antisense reverses adriamycin resistance," *J. of Biol. Chem.*, March 10, **2000**, *275(10)*, 7138-7143
	25	Lundt, I., et al., "Deoxyiminoalditols from aldonolactones; IV: preparation of 1,5-dideoxy-1,5-iminoheptitols with L-*glycero*-D-*manno*, D-glycero-L-*gulo* and L-*glycero*-D-*altro* configuration," *Synthesis*, July **1995**, 787-794
	26	Mehta, G., et al., "A norbornyl route to azasugars: a new synthesis of deoxynojirimycin analogues," *Tetrahedron Letts*, **2000**, *41*, 5741-5745
	27	Mellor, H.R., "High-performance cation-exchange chromatography and pulsed amperometric detection for the separation, detection, and quantitation of N-alkylated imino sugars in biological samples," *Analytical Biochemistry*, XP-001055984, **2000**, *284*, 136-142
	28	Paulsen, H., et al., "Über monosaccharide mit stickstoffhaltigem siebenring," *Chem. Ber.*, **1967**, *100*, 512-520 (German language); Chemical Abstracts #3208 "Thymine nucleosides of 3-deoxy-d-xylo-hexose," page 3207
	29	Paulsen, H., et al., "Synthese und reaktionen von keto-piperidinosen," *Chem. Ber.*, **1967**, *100*, 802-815 (English Abstract)
	30	Platt, F.M., et al., "*N*-butyldeoxygalactonojirimycin inhibits glycolipid biosynthesis but does not affect *N*-linked oligosaccharide processing," *J. of Biol. Chem.*, October 28, **1994**, *269(43)*, 27108-27114

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	31	Platt, F.M., et al., "Prevention of lysosomal storage in tay-sachs mice treated with *N*-butyldeoxynojirimycin," *Science*, April 18, **1997**, *276*, 428-431
	32	Poitout, et al., "Synthesis of azasugars.[1] Part 1[2] Isomerization of polyhydroxylated piperidines," *Tetrahedron Letts.*, **1996**, *37(10)*, 1609-1612
	33	Rao, V.S., et al., "Regioselective eliminations in reactions of carbohydrate derivatives with superoxide, or with borohydride in 2-propanol," *Can. J. Chem.*, **1981**, *59*, 333-338
	34	Reitz, A.B., et al., "Pyrrolidine and piperidine aminosugars from dicarbonyl sugars in one step. Concise synthesis of 1-deoxyojirimycin," *Tetrahedron Letts.*, **1990**, *31(47)*, 6777-6780
	35	Schaller, C., et al., "Total synthesis of (+)- and (−)-1-deoxynojirimycin (1,5-dideoxy-1,5-imino-D- and L-glucitol) and of (+)- and (−)-1-deoxyidonojirimycin (1,5-dideoxy-1,5-imino-D- and L-iditol) via furoisoxazoline-3-aldehydes," *Carbohydrate Res.*, **1998**, *314*, 25-35
	36	Simons K., et al., "Functional rafts in cell membranes," *Nature*, June 5, **1997**, *387*, 569-572
	37	Subramanian, T., et al., "Synthesis of oxazolidinyl azacycles via ring-closing olefin metathesis: a practical entry to the synthesis of deoxy-azasugars and hydroxypyrrolizidines," *Tetrahedron Letts.*, **2001**, *42*, 4079-4082
	38	Uriel, C., et al., "A short and efficient synthesis of 1,5-dideoxy-1,5-imino-D-galactitol (1-deoxy-D-galactostatin) and 1,5-dideoxy-1,5-imino-L-altritol (1-deoxy-L-altrostatin) from D-galactose," *Synlett*, **1999**, *5*, 593-595
	39	Xu, Y.-M., et al., "A new approach to 1-deoxy-azasugars: asymmetric synthesis of 1-deoxymannojirimycin and 1-deoxyaltronojirimycin," *J. Chem. Sco. Perkin Trans.*, **1997**, *1*, 741-746

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FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES	Translation NO
	40	0 536 402 A	04/14/93	EPO		
	41	3-24057	02/01/91	Japanese	X abstract	
	42	WO 94/26714	11/24/94	PCT		
	43	WO 98/02161	01/22/98	PCT		
	44	WO 01/10429 A2	02/15/01	PCT		

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